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OCT 17 2008

510(k) Summary
for the Calvary Spine Intervertebral Body Fusion Cages

In accordance with 21 CFR 807.92 of the Federal Code of Regulations
the following 510(k) summary is submitted for the Calvary Spine Intervertebral Body Fusion Cages

Date Prepared: August 5, 2008

1. **Submitter:**
Calvary Spine LLC
308 North Wind Rd
Towson, MD 21204

Contact Person:
J.D. Webb
The OrthoMedix Group, Inc.
1001 Oakwood Blvd
Round Rock, TX 78681
Telephone: 512-388-0199

2. **Trade name:** Integra Cervical and Petra PLIF Lumbar Cages
Common Name: intervertebral body fusion device
Classification Name: intervertebral body fusion device - cervical
Intervertebral body fusion device - lumbar
21 CFR section 888.3080
ODP/MAX
Class II

3. **Predicate or legally marketed devices which are substantially equivalent:**
The Calvary Spine Intervertebral Body Fusion Cages are substantially equivalent to similar previously cleared cervical and lumbar intervertebral body fusion devices.

4. **Description of the device:**
The Integra Cervical Cage was developed as an intercorporal implant for anterior cervical spondylodesis. To prevent migration, the Integra Cervical Cage has teeth on its superior and inferior surfaces. A large window allows bony growth to form. It has two tantalum x-ray markers.

The Petra PLIF Lumbar Cage was developed as an implant for the posterior stabilization of the lumbar spinal column using a Posterior Lumbar Interbody Fusion (PLIF) technique. The Petra PLIF implant has ridges on both its inferior and superior surfaces to prevent migration, and two large graft windows which help facilitate bony integration. It is a curved shape to facilitate insertion using a PLIF approach. The design is a wedged configuration for ease of insertion.

Materials:
PEEK-OPTIMA LT1 polymer (ASTM F2026 Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications)

5. **Intended Use:**

The Integra Cervical Cage is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. Integra Cervical Cage implants are used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach at the C-3 to T-1 disc levels using autograft bone. Integra Cervical implant is to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

The Petra PLIF Cage System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Petra PLIF Cage implants are to be used with

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autogenous bone graft and implanted via an open posterior approach. The Petra PLIF Cages are to be used with supplemental fixation. Patients should have at least (6) months of non-operative treatment prior to treatment with an intervertebral cage.

6. **Comparison of the technological characteristics of the device to predicate and legally marketed devices:**
   The Calvary Spine Intervertebral Body Fusion Cages have the same indications and material, and similar designs as previously cleared devices.

7. **Summary of Nonclincal Tests**
   Tests performed according to ASTM F2077/F2267 indicate that the Interbody Calvary Spine Intervertebral Body Fusion Cages meet required mechanical strengths.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Calvary Spine, LLC
% The Orthomedix Group, Inc.
Mr. J.D. Webb
Official Correspondent
1001 Oakwood Boulevard
Round Rock, Texas 78681

OCT 17 2008

Re: K082260
Trade/Device Name: Integra Cervical Cage
Petra PLIF Lumbar Cage
Regulation Number: 21 CFR 888.3080
Regulation Names: Intervertebral body fusion device.
Regulatory Class: II
Product Code: MAX, ODP
Dated: August 5, 2008
Received: August 8, 2008

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K082260

Device Name: Integra Cervical Cage

Indications for Use:

The Integra Cervical Cage is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. Integra Cervical Cage implants are used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach at the C-3 to T-1 disc levels using autogenous bone graft. Integra Cervical implant is to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for mxm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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Indications for Use

510(k) Number (if known): K082260

Device Name: Petra PLIF Lumbar Cage

Indications for Use:

The Petra PLIF Cage System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Petra PLIF Cage implants are to be used with autogenous bone graft and implanted via an open posterior approach. The Petra PLIF Cages are to be used with supplemental fixation. Patients should have at least (6) months of non-operative treatment prior to treatment with an intervertebral cage.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark P Dyke for mkm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082260